IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

SHERRIE BAILEY, Plaintiff, v. **I-FLOW CORPORATION**; a Delaware corporation, **DJO, LLC,** a Delaware Corporation; **and DJO, INC,** f/k/a **DJ ORTHOPEDICS, INC.,** a Delaware corporation, and Defendants.	)	No. 09-CV-0531 WJ/DJS

JOINT STATUS REPORT AND PROVISIONAL DISCOVERY PLAN

Pursuant to Fed.R.Civ.P. 26(f), a meeting was held on July 20, 2001 at 9:30 a.m., by conference call, attended by:

For the Plaintiffs:

Paul M. Dominguez, Branch Law Firm

For Defendant I-Flow:

Robert J. Curtis, Civerolo Law Firm

Chad Layton and Mitchell Morinec, Segal Law Firm

For Defendants DJO, LLC and DJO, INC.:

Jacqueline Olexy, Madison, Harbour, & Mroz, PA

NATURE OF THE CASE

This is a product liability action involving alleged personal injuries to Sherrie Bailey who claims to have sustained serious, permanent and debilitating injury to her right shoulder as a result of a continuous infusion of anesthetic delivered by a pain pump and catheter as part of her shoulder surgery on March 1, 2005 and treatment therefor. It is

alleged that the anesthetic and pain pump are manufactured and/or distributed by one or more named defendants herein.

AMENDMENTS TO PLEADINGS AND JOINDER OF PARTIES

Plaintiff intends to file: a motion to amend the pleadings to add allegations regarding parent and successor liability.

Plaintiff should be allowed 30 days from the Rule 16 Scheduling Conference to amend pleadings and join additional parties, if any.

Defendant(s) should be allowed 120 days from the Rule 16 Scheduling Conference to amend pleadings and to join additional parties.

STIPULATIONS

The remaining parties hereto stipulate and agree that venue is properly laid in this District and that the United States District Court for the District of New Mexico has jurisdiction of the parties and the subject matter.

The parties are willing to further stipulate to the following facts:

1. I-Flow is a Delaware corporation with its principal place of business in Lake Forest, California.

2. DJO, Incorporated and DJO, LLC have filed each filed Motions to Dismiss.

3. The substantive law governing Plaintiff's claims is that of New Mexico.

PLAINTIFF'S CONTENTIONS

Concise Factual Summary of Plaintiff's Claims:

Pain pumps are medical devices used by orthopedic surgeons to manage post-operative pain. They deliver, by way of a catheter, continuous doses of pain relief medication which, as employed in Plaintiff's surgery, went directly into her shoulder for several days after surgery.

Continuous injection of these anesthetics directly into the shoulder can cause serious and permanent damage to the shoulder joint cartilage. The damage occurs when the

anesthetic kills the chondrocytes (shoulder cartilage cells) which causes cartilage to degenerate progressively and rapidly. Patients injured by pain pumps develop a condition called, "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible, disabling and extremely painful condition. These patients typically require additional surgeries, including complete shoulder joint replacement.

Beginning in the late 1990s, the pain pump manufacturers sought approval from the Food and Drug Administration (FDA) for the placement of the catheter in the shoulder joint space. Because of the lack of safety information, the FDA rejected I-Flow's applications – not once, but three times. I-Flow pointed out that McKinley had clearance for orthopedic surgery, and the FDA made McKinley remove their language. I-Flow entered into an entered into an agreement with DJO to expressly promote the pumps for orthopedic use; despite the fact that clearance was not granted. After DJO entered into the distribution agreement in 1999, it began to initiate studies as Scripps to study the efficacy of the pump in shoulder and knee surgery. During this process, the Institutional Review Board asked for information on whether the device was cleared for the uses proposed in the study. DJO hired a regulatory consultant to answer that question. The regulatory consultant in 1999 opined that the FDA had not cleared any orthopedic use for the device. DJO confronted I-Flow with its information on the lack of orthopedic clearance, but the end result was that the companies renegotiated the I-Flow DJO contract, and continued to sell the pumps as if they believed the pumps were cleared for orthopedic use. Despite this, the manufacturers of the pumps chose not to advise patients of these risks nor tell physicians that their FDA applications for infusion directly into the shoulder were rejected.

In 2004, multiple scholarly studies were published demonstrating the toxic effects of pain pump anesthetics on shoulder cartilage. By late 2005 and early 2006, the pain pump industry knew that notable orthopedic surgeons were reporting a significant number of

patients developed shoulder chondrolysis following intra-articular placement of a pain pump catheter. The physicians associated these injuries with the use of intra-articular pain pumps. These reports confirmed anecdotal reports that dated back to no later than 2004.

Plaintiff contends that had the defendant manufacturers conducted or otherwise attempted to perform studies the FDA sought in the 1990s, they would have readily determined that exposure to pain pump anesthetics over time in the shoulder is exceedingly dangerous and contraindicated.

When the FDA denied I-Flows request for this indication on three separate occasions, both I-Flow and DJO knew they could not lawfully promote the pain pumps for orthopedic use. However, I-Flow and DJO entered an agreement to promote the pain pumps for orthopedic use, in violation of FDA regulations. DJO and I-Flow agreed that if apprehended, they would claim that orthopedic use was included within the general use permitted by the agency – despite the fact that regulatory consultants advised that orthopedic use was not permitted. I-Flow and DJO defendants acted with a common goal of selling pain pumps to orthopedic surgeons, for orthopedic/intra-articular/synovial cavity use and making a profit from those sales, despite the fact that promoting pumps for orthopedic use was contrary to federal law.

DJO had specific knowledge that I-Flow's continued sales of pain pumps to orthopedic surgeons was contrary to federal law, and constituted a breach of its duty of care to the orthopedic surgeons who were unknowingly engaged in an off-label use of I-Flow pain pumps. DJO gave substantial assistance and encouragement to I-Flow, which allowed it to continue its unlawful sales of pain pumps even after DJO ceased being its distributor.

Because DJO entered into a civil conspiracy with I-Flow to unlawfully promote pain pumps as alleged above, DJO defendants are jointly liable to those harmed by I-Flow's

conduct. Plaintiff alleges joint liability of DJO defendants for all acts alleged herein and committed by defendant I-Flow.

DJO, Inc. is liable because it exercised control over DJO, LLC by using DJO, LLC's resources as its own, by commingling assets, by holding itself out to the public as one company, and because the parent companies only exist on paper and have no separate location or existence. DJO, Inc. essentially used DJO, LLC to manufacture, market and distribute the pain pumps to the public.

DEFENDANTS' CONTENTIONS

DJO, LLC and DJO, Incorporated have moved to dismiss Plaintiff's complaint on the grounds that it fails to state a claim upon which relief can be granted. Plaintiff does not allege that either DJO, LLC or DJO, Incorporated designed, manufactured, marketed, or sold the pain pump at issue. Further, Plaintiff does not allege that DJO, Incorporated or DJO, LLC distributed the pain pump that Plaintiff claims caused her injuries. To the extent that Plaintiff's claims rest on a theory of civil conspiracy, Plaintiff's Amended Complaint fails to meet the most basic pleading requirements to assert a claim for civil conspiracy under New Mexico law.

I-Flow has filed a motion to dismiss some of plaintiff's claims. I-Flow denies Plaintiff's contentions and asserts affirmative defenses consistent with those set forth in its answer. I-Flow specifically contests product identification and disputes there is a defect in its products, if any such product is at issue in this case. I-Flow denies any negligence on its part and Plaintiff's claim that she is entitled to compensatory damages from I-Flow. I-Flow denies it is liable for products liability, failure to warn, design defect or any other claim in plaintiff's complaint. I-Flow denies it is liable for plaintiff's damages including punitive damages.

PROVISIONAL DISCOVERY PLAN

Discovery will be needed on the following subjects:

- ☐ Product identification
- ☐ Liability
- ☐ General causation
- ☐ Specific causation
- ☐ Damages, if any

Maximum of 50 interrogatories by each party to any other party. Maximum of 50 requests for admission by each party to any other party. Maximum of ten depositions by Plaintiff(s) and 15 by Defendant(s).

Each deposition (other than of a party or an expert) limited to maximum of 4 hours unless extended by agreement of parties.

Disclosure of and reports from retained experts under Rule 26(a)(2) due:

from Plaintiff(s) at a time established by the Court.

from Defendant(s) 45 days after the date established by the Court for Plaintiffs to disclose experts.

Supplementation under Rule 26(e) due within a reasonable time after discovery of the supplemental or corrected information.

All discovery commenced in time to be complete by _____.

Other Items: A confidentiality order approved by the Court must be entered into the record prior to Defendants production of any documents or materials.

PRETRIAL MOTIONS

Plaintiff intends to file: Unknown at this time

Defendant intends to file: Motion for summary judgment; *Daubert* motion(s).

- DJ Orthopedics, Incorporated: Not known at this time.
- DJ, LLC: Not known at this time.

ESTIMATED TRIAL TIME

The parties estimate trial will require 5-7 days.

____ This is a non-jury case.

_X_ This is a jury case.

The parties request a pretrial conference a month to six weeks prior to trial.

SETTLEMENT

The possibility of settlement in this case cannot be evaluated prior to the close of discovery and may be enhanced by use of mediation. The parties request a settlement conference after the close of merits discovery.

EXCEPTIONS

None.

APPROVED:

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